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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/569,021	11/20/2008	Richard W. LeVaughn	2G021-082 1	9120
23506 7590 12/20/2011 GARDNER GROFF GREENWALD & VILLANUEVA, PC 2018 POWERS FERRY ROAD SUITE 800 ATLANTA, GA 30339				
EXAMINER TANNER, JOCELYN C				
ART UNIT 3731		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patent@gardnnergroff.com

Office Action Summary**Application No.**

10/569,021

Applicant(s)

LEVAUGHN ET AL.

Examiner

JOCELIN TANNER

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-42 is/are pending in the application.
- 5a) Of the above claim(s) 23-26 and 28-42 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-22 and 27 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☒ The drawing(s) filed on 17 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (Claims 1-22 and 27) in the reply filed on 21 November 2011 is acknowledged. Claims 23-26, 28-32, 41 and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 21 November 2011.

2. Applicant's election with traverse of Group V (claims 33-40) in the reply filed on 21 November 2011 is acknowledged. The traversal is on the ground(s) that Groups I and V include a number of common or substantially related elements and it will likely be necessary for the Examiner to also search art relevant to claims in Group V as well. This is not found persuasive because additional and different search queries would be required to search for the features of the cassette than when searching for the lancing device, therefore, a serious burden would be placed on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claim 9, the recitation "each lancet comprises a follower in engagement with a cooperating cam surface" is confusing. The instant specification [0056] describes the separation of the lancet from the endcap as involving follower (191) on the lancet cap which does not appear to be part of the lancet but part of the endcap in figure 3.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 2, 5, 6, 12-16, 20, 21 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Levaughn et al. (US PGPub No. 2004/0230216A1- Embodiment of Figs. 19-28).

8. Regarding claim 1, Levaughn et al. discloses a lancing device including a plurality of lancets (144) positioned in a planar array, the planar array defining a storage plane, wherein an active lancet selected from the plurality of lancets is capable of being transversely displaced out of the storage plane into a firing plane that is generally parallel to the storage plane (Figs. 19-28).

9. Regarding claim 2, Levaughn et al. discloses the plurality of lancets are positioned in a circular pattern within the planar array, with sharp tips of the lancets oriented radially outward ([0111], Fig. 19).
10. Regarding claim 5, Levaughn et al. discloses the active lancet being capable of moving into engagement with a drive mechanism (184) as it is transversely displaced out of the storage plane [0112-0114].
11. Regarding claim 6, Levaughn et al. discloses each lancet including a T-shaped end for engagement with a slotted coupling (198) on a piston ([0113], Fig. 19).
12. Regarding claim 12, Levaughn et al. discloses the active lancet as being capable of being guided by a drive mechanism (184) along a lancing path in the firing plane, between a retracted position within a housing of the lancing device and an extended position, wherein at least a sharp tip portion of the active lancet is capable of extending outwardly from the housing after the cap (174) is removed therefrom [0113-0114].
13. Regarding claim 13, Levaughn et al. discloses the housing as having a base (178), a cover defining an opening and a movable door for selectively uncovering the opening (Fig. 21).
14. Regarding claim 14, Levaughn et al. discloses the plurality of lancets as being contained within a disposable cassette that is removably installed within a reusable housing (Fig. 19).
15. Regarding claim 15, Levaughn et al. discloses a biasing member positioned over the plurality of lancets such that when the cover is removed the biasing member is capable of assisting in the removal of the disposable cassette (Fig. 19).

16. Regarding claim **16**, Levaughn et al. discloses a cap or "tab" that is capable of being broken away from the cassette (Fig. 19).

17. Regarding claims **20 and 21**, Levaughn et al. discloses a used lancet that is capable of being returned from the firing plane to the storage plane in an axially-offset position to prevent reuse [0118].

18. Regarding claim **27**, Levaughn et al. discloses a device including a plurality of lancets, an advancing mechanism capable of advancing each of the plurality of lancets sequentially into an active position, a drive mechanism for propelling an active lancet from a retracted position to a lancing position, wherein the advancing mechanism includes an arming lever (202) that is rotationally actuated to advance the lancets and linearly retracted to energize the drive mechanism [0114].

19. Claims 1, 14 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Levaughn et al. (US PGPub No. 2004/0230216A1-Embodiment of Figs. 29-32).

20. Regarding claim **1**, Levaughn et al. discloses a lancing device including a plurality of lancets positioned in a planar array, the planar array defining a storage plane, wherein an active lancet selected from the plurality of lancets is capable of being transversely displaced out of the storage plane into a firing plane that is generally parallel to the storage plane (Fig. 29).

21. Regarding claim **14**, Levaughn et al. discloses the plurality of lancets as being contained within a disposable cassette that is removably installed within a reusable housing (Figs. 4, 30).

22. Regarding claim **17-19**, Levaughn et al. discloses an advancing mechanism including a rotational arming lever (256) having a pawl for cooperative engagement with teeth of the disposable cassette for moving lancets sequentially into an active position, the pawl being pivotally coupled to the rotational arming lever, the rotational arming lever including a cam path for cooperative engagement with a follower portion of a drive mechanism (250), and wherein rotational actuation of the arming lever energizes the drive mechanism (Fig. 29, [0119-0121]).

23. Claims 1, 5, 8-11 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuhr et al. (US PGPub No. 2004/0230216A1).

24. Regarding claims **1, 5, 8, 10, 11 and 22**, Kuhr et al. discloses a lancing device including a plurality of lancets positioned in a planar array, the planar array defining a storage plane, wherein an active lancet selected from the plurality of lancets is capable of being transversely displaced out of the storage plane into a firing plane that is generally parallel to the storage plane, wherein a user is capable of transversely displacing the active lancet by disposing a lancing holder (19) around the active lancet, ejecting a protective sheath (14) and removing the lancet from a magazine or "storage plane" (1) and then moving the lancing holder transversely to the magazine to fire the lancet, a drive mechanism is tensioned as a protecting cap (18) is replaced onto the lancing holder, the lancet being capable of being constrained against axial movement as the endcap is separated therefrom, the endcap including at least one extensible arm extending laterally therefrom, the removable endcap of each lancet including at least

one extensible arm (24) that extending laterally therefrom (column 11, lines 25-67, column 12, lines 1-20, column 14, lines 35-40, Figs. 3).

25. Regarding claim 9, as best understood, Kuhr et al. discloses each lancet including a follower (22) in engagement with a cooperating cam surface of the holder that assists in separating the endcap from the active lance (column 13, lines 25-50).

26. **Claims 1-5, 12-14, 20 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Lipoma et al. (US PGPub No. 2005/0033340A1).**

27. Regarding claim 1, Lipoma et al. discloses a lancing device including a plurality of lancets (5) positioned in a planar array, the planar array defining a storage plane, wherein an active lancet selected from the plurality of lancets is capable of being transversely displaced out of the storage plane into a firing plane that is generally parallel to the storage plane (Fig. 1).

28. Regarding claim 2, Lipoma et al. discloses the plurality of lancets are positioned in a circular pattern within the planar array, with sharp tips of the lancets oriented radially outward (Fig. 6).

29. Regarding claim 3, Lipoma et al. discloses an active lance being transversely displaced out of the storage plane into a firing plane upon rotational advancement of the lancets [0028].

30. Regarding claim 4, Lipoma et al. discloses a cam surface (13) capable of transversely displacing the active lancet into the firing plane.

31. Regarding claim 5, Lipoma et al. discloses the active lancet being capable of moving into engagement with a drive mechanism (14) as it is transversely displaced out of the storage plane (Fig. 5, [0024]).
32. Regarding claim 12, Lipoma et al. discloses the active lancet as being capable of being guided by a drive mechanism (14) along a lancing path in the firing plane, between a retracted position within a housing of the lancing device and an extended position, wherein at least a sharp tip portion of the active lancet is capable of extending outwardly from the housing [0024].
33. Regarding claim 13, Lipoma et al. discloses the housing as having a base (4b), a cover (4a) defining an opening and an edge of the cover or "movable door" capable of selectively uncovering the opening (Fig. 1).
34. Regarding claim 14, Lipoma et al. discloses the plurality of lancets as being contained within a disposable cassette that is removably installed within a reusable housing (Fig. 1).
35. Regarding claims 20 and 21, discloses a used lancet that is capable of being returned from the firing plane to the storage plane in an axially-offset position to prevent reuse [0024].
- 36. Claims 1-3, 5, 12-14, 20 and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Boecker et al. (US PGPub No. 2003/0199894A1).**
37. Regarding claim 1, Boecker et al. discloses a lancing device including a plurality of lancets (18) positioned in a planar array, the planar array defining a storage plane, wherein an active lancet selected from the plurality of lancets is capable of being

transversely displaced out of the storage plane into a firing plane that is generally parallel to the storage plane (Fig. 1).

38. Regarding claim **2**, Boecker et al. discloses the plurality of lancets are positioned in a circular pattern within the planar array, with sharp tips of the lancets oriented radially outward (Fig. 2).

39. Regarding claim **3**, Boecker et al. discloses an active lance being transversely displaced out of the storage plane into a firing plane upon rotational advancement of the lancets [0095].

40. Regarding claim **5**, Boecker et al. discloses the active lancet being capable of moving into engagement with a drive mechanism as it is transversely displaced out of the storage plane (Fig. 6, [0089]).

41. Regarding claim **12**, Boecker et al. discloses the active lancet as being capable of being guided by a drive mechanism along a lancing path in the firing plane, between a retracted position within a housing of the lancing device and an extended position, wherein at least a sharp tip portion of the active lancet is capable of extending outwardly from the housing [0095].

42. Regarding claim **13**, Boecker et al. discloses the housing as having a base (46), a cover (52) defining an opening and a movable door (48) capable of selectively uncovering the opening (Fig. 1).

43. Regarding claim **14**, Boecker et al. discloses the plurality of lancets as being contained within a disposable cassette that is removably installed within a reusable housing (Fig. 1).

44. Regarding claims **20 and 21**, discloses a used lancet that is capable of being returned from the firing plane to the storage plane in an axially-offset position to prevent reuse [0095].

Claim Rejections - 35 USC § 103

45. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

46. **Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhr et al. (US PGPub No. 2004/0230216A1) in view of Mace (US PGPub No. 2004/0267300A1).**

47. Regarding claim 7, Kuhr et al. discloses all of the limitations previously discussed except for each lancet having a ball-shaped end for engagement with a socket coupling on a piston portion of the drive mechanism.

Mace teaches a lancet device including a lance (73) having a ball-shaped end and a piston portion (71) of the drive mechanism including a socket coupling (Fig. 3). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the lancet of Kuhr with a lancet having a ball-shaped end, as taught by Mace, as this modification involves the simple substitution of one type of lancet for another for the predictable result of providing means of piercing skin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Hughes can be reached on 571-272-4357. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to

TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
12/14/2011
Examiner, Art Unit 3731

/Kathleen Sonnett/
Primary Examiner, Art Unit 3731